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EXAMINER CROW, ROBERT THOMAS				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/526,402

Applicant(s)

KIM ET AL.

Examiner

Robert T. Crow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-27 and 29-31 is/are pending in the application.
- 4a) Of the above claim(s) 9-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-8, 26, 27 and 29-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/888)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10 September 2008 has been entered.

Status of the Claims

2. This action is in response to papers filed 10 September 2008 in which claims 1-2 and 4-5 were amended, claims 3 and 28 were canceled, and new claims 30-31 were added. All of the amendments have been thoroughly reviewed and entered.

The objection to claim 2 listed in the previous Office Action are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(a,b,e) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

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3. Previously withdrawn claim 4 has been amended to be dependent upon claim 1. Claim 4 is therefore rejoined.

4. Claims 1-2, 4-8, 26-27, and 29-31 are under prosecution.

Claim Objections

5. Claim 4 is objected to because of the following informalities: claim 4 is drawn to "[t]he coating solution according to claim 1." However, claim 1 is drawn to a biochip, not a coating solution.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 5-6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)).

Regarding claim 5, Kim et al teach a chip substrate in the form of a glass slide coated with a coating solution consisting of polyvinyl acetate (i.e., PVAc,

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Figure 1) having a molecular weight of 130,000 (page 332, "Materials" section) dissolved in methylene chloride (page 33, column 1).

Regarding claim 6, the substrate of claim 5 is discussed above. The courts have stated:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP § 2113.

While Kim et al do not specifically teach spin coating, these limitations are part of the process of making the chip substrate rather than structural limitations of the chip substrate. Because Kim et al teach the structural elements of independent claim 5, claim 6 is also anticipated by Kim et al.

Regarding claim 8, Kim et al teach the chip substrate of claim 5, wherein the substrate has a slide shape; namely, the substrate is a slide (Figure 1).

Response to Arguments

Applicant's arguments filed 11 August 2008 (hereafter the "Remarks") have been fully considered but they are not persuasive for the reasons listed below.

A. Applicant argues on pages 14-15 of the Remarks that Kim et al does not teach the biomaterials are entrapped in pores of gel spots on a chip

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substrate, wherein the claimed gels spots are integrated in an amount of up to 1000 spots/cm² as recited in claims 1 and 30.

However, it is noted that claims 5-6 and 8 are merely drawn to a chip substrate coated with a coating solution, and thus do not require gel spots, biomaterials, or any of the other limitations argued by Applicant on pages 14-16 of the Remarks. The claims therefore remain rejected as anticipated by Kim et al as discussed above.

B. Applicant's arguments on pages 16-21 of the Remarks with respect to the previous rejections of the claims based on the prior art of Anderson et al and Dordick et al have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

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and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-2, 26-27, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996).

Regarding claim 1, Kim et al teach a biochip. In a single exemplary embodiment, Kim et al teach Figure 1, which shows a biochip comprising a chip substrate in the form of a polyvinyl acetate coated glass slide having gel spots in the form of sol-gel microstructures in strips (i.e., spots) thereon. The sol-gel spots are immobilized on the slide because the spots are retained by the polyvinyl acetate (i.e., PVAc) coating (page 336, column 1, last full paragraph); and the polyvinyl acetate coating has a molecular weight of 130,000 (page 332, "Materials" section) dissolved in methylene chloride (page 33, column 1). The gel spots have pores therein in the form of microchannels (page 332, column 1, first full paragraph), and active proteins, which are biomaterials, are contained within the sol-gel spots (Figure 1). The biomaterials have a free orientation without being immobilized because they are entrapped within the pores (i.e., microchannel network; page 332, column 1, first full paragraph and page 333, column 1). Because the biomaterials are entrapped within the gel, there is not

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covalent bond to the gel. The gel spots are formed by the gelation of a sol mixture on the substrate (page 333, columns 1-2).

While Kim et al do not specifically teach the spots are circular, the courts have found that changes in shape are obvious (*In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)). Thus, circular shape of the spots of the instant claim is an obvious variant of the spots Kim et al. See MPEP 2144.04 [R-6] IV B.

Kim et al do not teach the substrate is a polycarbonate substrate.

However, Simon et al teach a slide substrate made of polycarbonate, which has the added advantage of being made by plastic injection molding, thereby producing a precision slide by simple manufacturing techniques (column 1, line 59-column 2, line 10). Thus, Simon et al teach the known technique of using a polycarbonate substrate.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip substrate as taught by Kim et al by using the polycarbonate substrate of Simon et al as the chip substrate to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a chip substrate having the added advantage of having a precision slide made by simple manufacturing techniques as explicitly taught by Simon et al (column 1, line 59-column 2, line 10). In addition, it would have been obvious to the ordinary artisan that the known technique of using the polycarbonate substrate of Simon et al could have been used as the chip substrate of Kim et al with predictable

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results because the polycarbonate substrate of Simon et al predictably results in a substrate useful for evaluation of specimen liquids.

Regarding claim 2, the biochip of claim 1 is discussed above. Kim et al teach the chip is used as a protein chip; namely proteins are entrapped in the chip (page 333, column 1).

In addition, it is noted that the courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 2 (e.g., use as a protein chip) fail to define additional structural elements to the device of independent claim 1. Because the prior art teaches the structural elements of the claim, the claim 2 is obvious over the prior art. See MPEP § 2114.

Regarding claims 26-27, the biochip of claim 1 is discussed above. Kim et al teach the biochip of claim 1, wherein the biomaterials are IgG (page 333, column 1), which are antigens to anti-human polyvalent IgG (i.e., claim 27) and are proteins (i.e., claim 28).

It is noted that the broadly claimed "antigens or antibodies for infectious disease diagnosis" of claim 27 does not necessarily require the antigens to be

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"for infections disease diagnosis" due to the placement of the word "or" in the recitation.

Regarding claim 30, the biochip of claim 1 is discussed above. Kim et al also teach the gel spots are integrated in an amount of up to 1000 spots/cm²; namely, Figure 4 shows 5 spots of gel in an area approximately 1000 microns (0.1 cm) by about 700 microns (0.07 cm), based on the 100 micron bar in the Figure. The spot density is therefore $(5 \text{ spots}) / (0.1 \text{ cm}) \times (0.07 \text{ cm}) =$ approximately 714 spots/cm².

Response to Arguments

Applicant's arguments on pages 12-16 of the Remarks with respect to the previous rejections of the claims as anticipated by Kim et al have been considered.

While the arguments are moot in view of the new ground(s) of rejection necessitated by the amendments, the arguments relative to the teachings of Kim et al detailed in the instant rejections and the arguments regarding the alleged improved reactivity and sensitivity of the claimed biochip are considered below.

A. Applicant argues on page 14 of the Remarks that the claimed biochip has improved reactivity and sensitivity because large amounts of biomaterials can be contained in gel spots while maintaining its 3-dimensional structure.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant

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relies (i.e., "large amounts of biomaterials" and maintained 3-dimensional structure) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In addition, Kim et al clearly teach the sol-gel encapsulated proteins "exhibit improved resistance the thermal and chemical denaturation (column 2, page 331)." Thus Kim et al clearly teach encapsulated biomaterials, in the form of proteins, that are not denatured, and therefore have maintained 3-dimensional structure.

B. Applicant argues on page 15 of the Remarks that the present invention is further interested in the morphology of the spots.

However, as noted above, while Kim et al do not specifically teach the spots are circular, the courts have found that changes in shape are obvious (*In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)). Thus, circular shape of the spots of the instant claim is an obvious variant of the spots Kim et al. See MPEP 2144.04 [R-6] IV B.

Further, as detailed in the rejections below, circular gel spots were well known in the art at the time the claimed invention was made; e.g., as taught by Maracas et al.

C. Applicant argues on page 15 of the Remarks that adhesion between the spot type and the chip substrate is important, and that the spots have spherical morphology.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the structural limitations resulting in the adhesion between the spot type and spherical morphology) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

D. Applicant argues on page 15 of the Remarks that gelation on the chip substrate is promoted and the coating maintains the shape of the spots.

However, Kim et al clearly teach gelation occurs on the chip substrate (i.e., PVAc coated slide) and that the spot shape is maintained (Figures 1 and 4).

11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996) as applied to claim 1 above, and further in view of Malhorta (U.S. Patent No. 5,624,743, issued 29 April 1997).

Regarding claim 4, the biochip of claim 1 is discussed above in Section 10.

While Kim et al teach the polyvinyl acetate solution is in methylene chloride (page 333, first paragraph), neither Kim et al nor Simon et al teach the solvent is 5-20% by weight.

However, Malhorta teaches polyvinyl acetate solutions in about 10 to about 30 percent by weight (column 7, lines 40-60), which includes the claimed value of 20% by weight. Thus, Malhorta teaches the known technique of using a polyvinyl acetate solution having methylene chloride in 20% by weight.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip substrate having a coating solution of polyvinyl acetate in methylene chloride as taught by Kim et al in view of Simon et al so that the coating solution is a polyvinyl acetate solution having methylene chloride in 20% by weight as taught by Malhorta to arrive at the instantly claimed invention with a reasonable expectation of success. It would have been obvious to the ordinary artisan that the known technique of using the polyvinyl acetate solution having methylene chloride in 20% by weight as taught by Malhorta could have been used as the coating solution in the chip substrate of Kim et al in view of Simon et al with predictable results because the known technique of using the polyvinyl acetate solution having methylene chloride in 20% by weight as taught by Malhorta predictably results in a useful coating solution concentration.

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) as applied to claim 5 above, and further in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996).

Regarding claim 7, the chip substrate of claim 5 is discussed above in Section 7.

Kim et al does not teach the substrate is a polycarbonate substrate.

However, Simon et al teach a slide substrate made of polycarbonate, which has the added advantage of being made by plastic injection molding, thereby producing a precision slide by simple manufacturing techniques (column 1, line 59-column 2, line 10). Thus, Simon et al teach the known technique of using a polycarbonate substrate.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip substrate as taught by Kim et al by using the polycarbonate substrate of Simon et al as the chip substrate to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a chip substrate having the added advantage of having a precision slide made by simple manufacturing techniques as explicitly taught by Simon et al (column 1, line 59-column 2, line 10). In addition, it would have been obvious to the ordinary artisan that the known technique of using the polycarbonate substrate of Simon et al could have been used as the chip substrate of Kim et al of with predictable results because the polycarbonate substrate of Simon et al predictably results in a substrate useful for evaluation of specimen liquids.

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13. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996) as applied to claims 1 and 27 above, and further in view of Croxson (U.S. Patent No. 5,108,891, issued 28 April 1992).

Regarding claim 29, the biochip of claims 1 and 27 is discussed above in Section 10.

While Kim et al teach the biomaterials are proteins in the form of IgG (page 333, column 1), which is a protein, neither Kim et al nor Simon et al specifically teach the protein is HIV p24 (i.e., claims 27 and 29).

However, Croxson teaches the binding of molecules to protein HIV p24 (Abstract), wherein HIV p24 has the added advantage of being an indicator of the progression of HIV to AIDS (column 1, lines 40-67). Thus, Croxson teaches the known technique of binding molecules to HIV p24.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the biochip as taught by Kim et al in view of Simon et al so that the immobilized protein biomaterial on the biochip is the HIV p24 protein of Croxson to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a biochip having the added advantage of allowing the assays performed with the biochip to indicate the progression of HIV to AIDS as explicitly taught by Croxson (column 1, lines 40-67). In addition, it

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would have been obvious to the ordinary artisan that the known technique of using the HIV p24 of Croxson could have been used as the biomaterial in the biochip of Kim et al in view of Simon et al with predictable results because the HIV p24 of Croxson predictably results in a substrate useful for evaluation of the HIV progression in a patient.

14. It is noted that while claims 1-2, 4, 26-27, and 29-30 have been rejected under 35 USC 103(a) as described above in Sections 10 and 13, the claims are also obvious using the alternate interpretation detailed below.

15. Claims 1-2, 26-27, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996) in view of Maracas et al (U.S. Patent No. 5,725,788, issue 10 March 1998).

Regarding claim 1, Kim et al teach a biochip. In a single exemplary embodiment, Kim et al teach Figure 1, which shows a biochip comprising a chip substrate in the form of a polyvinyl acetate coated glass slide having gel spots in the form of sol-gel microstructures in strips (i.e., spots) thereon. The sol-gel spots are immobilized on the slide because the spots are retained by the polyvinyl acetate (i.e., PVAc) coating (page 336, column 1, last full paragraph); and the polyvinyl acetate coating has a molecular weight of 130,000 (page 332, "Materials" section) dissolved in methylene chloride (page 33, column 1). The

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gel spots have pores therein in the form of microchannels (page 332, column 1, first full paragraph), and active proteins, which are biomaterials, are contained within the sol-gel spots (Figure 1). The biomaterials have a free orientation without being immobilized because they are entrapped within the pores (i.e., microchannel network; page 332, column 1, first full paragraph and page 333, column 1). Because the biomaterials are entrapped within the gel, there is not covalent bond to the gel. The gel spots are formed by the gelation of a sol mixture on the substrate (page 333, columns 1-2).

Kim et al do not teach the substrate is a polycarbonate substrate.

However, Simon et al teach a slide substrate made of polycarbonate, which has the added advantage of being made by plastic injection molding, thereby producing a precision slide by simple manufacturing techniques (column 1, line 59-column 2, line 10). Thus, Simon et al teach the known technique of using a polycarbonate substrate.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip substrate as taught by Kim et al by using the polycarbonate substrate of Simon et al as the chip substrate to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a chip substrate having the added advantage of having a precision slide made by simple manufacturing techniques as explicitly taught by Simon et al (column 1, line 59-column 2, line 10). In addition, it would have been obvious to the ordinary

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artisan that the known technique of using the polycarbonate substrate of Simon et al could have been used as the chip substrate of Kim et al of with predictable results because the polycarbonate substrate of Simon et al predictably results in a substrate useful for evaluation of specimen liquids.

While Kim et al teach the spots are formed via patterning using a stamp (Figure 1), neither Kim et al nor Simon et al teach the spots formed by the stamp are circular.

However, Maracas et al teach biochips in the form of arrays of monolayer features (i.e., spots; Abstract), wherein the array is produced using a polydimethylsiloxane (i.e., PDMS) stamp producing circular spots of 0.1-1000 microns (Figure 1 and column 3, lines 35-55), which encompasses the claimed range of 100-500 microns. Maracas et al also teach the stamp has the added advantage of producing patterns quickly, easily, and reproducibly with low cost and low maintenance (column 1, lines 40-50). Thus, Maracas et al teach the spots formed by the stamp are circular spots.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the biochip comprising gels spots created with a PDMS stamp as taught by Kim et al in view of Simon et al by using the PDMS stamp producing the circular spots polycarbonate substrate as taught by Maracas et al to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification

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would have resulted in a chip substrate having the added advantage of using a stamp that produces patterns quickly, easily, and reproducibly with low cost and low maintenance as explicitly taught by Maracas et al (column 1, lines 40-50). In addition, it would have been obvious to the ordinary artisan that the known technique of using the stamp making the circular spots of Maracas et al could have been used to form the chip substrate of Kim et al in view of Simon et al with predictable results because the known technique of using the stamp making the circular spots of Maracas et al predictably results in a spot sizes useful for arrays

Regarding claim 2, the biochip of claim 1 is discussed above. Kim et al teach the chip is used as a protein chip; namely proteins are entrapped in the chip (page 333, column 1).

In addition, as noted above, apparatus claims cover what a device *is*, not what a device *does*. Therefore, the various uses recited in claim 2 (e.g., use as a protein chip) fail to define additional structural elements to the device of independent claim 1. Because the prior art teaches the structural elements of the claim, the claim is obvious over the prior art.

Regarding claims 26-27, the biochip of claim 1 is discussed above. Kim et al teach the biochip of claim 1, wherein the biomaterials are IgG (page 333, column 1), which are antigens to anti-human polyvalent IgG (i.e., claim 27) and are proteins (i.e., claim 28).

It is noted that the broadly claimed "antigens or antibodies for infectious disease diagnosis" of claim 27 does not necessarily require the antigens to be

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"for infections disease diagnosis" due to the placement of the word "or" in the recitation.

Regarding claim 31, the biochip of claim 1 is discussed above. Maracas et al teach the spot diameter is 0.1-1000 microns (Figure 1 and column 3, lines 35-55), which encompasses the claimed range of 100-500 microns. Thus, modification of the biochip of Kim et al in view of Simon et al with the teachings of Maracas et al results in a biochip wherein the gel spots are 100-500 microns.

16. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996) in view of Maracas et al (U.S. Patent No. 5,725,788, issue 10 March 1998) as applied to claim 1 above, and further in view of Malhorta (U.S. Patent No. 5,624,743, issued 29 April 1997).

Regarding claim 15, the biochip of claim 1 is discussed above in Section 15.

While Kim et al teach the polyvinyl acetate solution is in methylene chloride (page 333, first paragraph), neither Kim et al, Simon et al, nor Maracas et al teach the solvent is 5-20% by weight.

However, Malhorta teaches polyvinyl acetate solutions in about 10 to about 30 percent by weight (column 7, lines 40-60), which includes the claimed value of 20% by weight. Thus, Malhorta teaches the known technique of using a polyvinyl acetate solution having methylene chloride in 20% by weight.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip substrate having a coating solution of polyvinyl acetate in methylene chloride as taught by Kim et al in view of Simon et al and Maracas et al so that the coating solution is a polyvinyl acetate solution having methylene chloride in 20% by weight as taught by Malhorta to arrive at the instantly claimed invention with a reasonable expectation of success. It would have been obvious to the ordinary artisan that the known technique of using the polyvinyl acetate solution having methylene chloride in 20% by weight as taught by Malhorta could have been used as the coating solution in the chip substrate of Kim et al in view of Simon et al and Maracas et al with predictable results because the known technique of using the polyvinyl acetate solution having methylene chloride in 20% by weight as taught by Malhorta predictably results in a useful coating solution concentration.

17. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996) in view of Maracas et al (U.S. Patent No. 5,725,788, issue 10 March 1998) as applied to claims 1 and 27 above, and further in view of Croxson (U.S. Patent No. 5,108,891, issued 28 April 1992).

Regarding claim 29, the biochip of claims 1 and 27 is discussed above in Section 15.

While Kim et al teach the biomaterials are proteins in the form of IgG (page 333, column 1), which is a protein, neither Kim et al, Simon et al, nor Maracas et al specifically teach the protein is HIV p24 (i.e., claims 27 and 29).

However, Croxson teaches the binding of molecules to protein HIV p24 (Abstract), wherein HIV p24 has the added advantage of being an indicator of the progression of HIV to AIDS (column 1, lines 40-67). Thus, Croxson teaches the known technique of binding molecules to HIV p24.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the biochip as taught by Kim et al in view of Simon et al and Maracas et al so that the immobilized protein biomaterial on the biochip is the HIV p24 protein of Croxson to arrive at the instantly claimed invention with a reasonable expectation of success. The ordinary artisan would have been motivated to make the modification because said modification would have resulted in a biochip having the added advantage of allowing the assays performed with the biochip to indicate the progression of HIV to AIDS as explicitly taught by Croxson (column 1, lines 40-67). In addition, it would have been obvious to the ordinary artisan that the known technique of using the HIV p24 of Croxson could have been used as the biomaterial in the biochip of Kim et al in view of Simon et al and Maracas et al with predictable results because the HIV p24 of Croxson predictably results in a substrate useful for evaluation of the HIV progression in a patient.

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18. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biotechnology and Bioengineering, vol. 73, pages 331-337 (5 June 2001)) in view of Simon et al (U.S. Patent No. 5,569,607, issued 29 October 1996) in view of Maracas et al (U.S. Patent No. 5,725,788, issue 10 March 1998) as applied to claim 1 above, and further in view of Fang et al (U.S. Patent Application Publication No. US 2002/0094544 A1, published 18 July 2002).

Regarding claim 30, the biochip of claim 1 is discussed above in Section 15.

While Maracas et al teach the spot diameters encompassing the claimed range of 100-500 microns (column 3, lines 35-55), neither Kim et al, Simon et al, nor Maracas et al explicitly teach circular spot densities of up to 1000 spots/cm².

However, Fang et al teach arrays of circular spots having a density that preferentially does not exceed 1000 spots/cm² (paragraph 0057). Thus, Fang et al teaches the known preferred technique or providing spot densities of less than (i.e., up to) 1000 spots/cm².

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the biochip as taught by Kim et al in view of Simon et al and Maracas et al so that the density of spots is less than (i.e., up to) 1000 spots/cm² as taught by Fang et al to arrive at the instantly claimed invention with a reasonable expectation of success. It would have been obvious to the ordinary artisan that the known preferred technique or providing spot densities of less than (i.e., up to) 1000 spots/cm² as taught by Fang et al could have been used as a limit to the spot density of the biochip of

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Kim et al in view of Simon et al and Maracas et al with predictable results because the known preferred technique or providing spot densities of less than (i.e., up to) 1000 spots/cm² as taught by Fang et al predictably results in a spot density that is easily readable (e.g., Figure 9).

Response to Arguments

Applicant's arguments regarding teachings of Simon et al and Croxson et al rely on the alleged deficiencies of the previously cited primary references, and thus do not challenge the teachings of Simon et al or Croxson et al. Because the instant rejections are new rejections necessitated by the amendments, Applicant's arguments regarding Simon et al and Croxson et al are moot in view of the new rejections necessitated by the amendments.

Conclusion

19. No claim is allowed.
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571)272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Robert T. Crow/
Examiner, Art Unit 1634

Robert T. Crow
Examiner
Art Unit 1634